HERMES DECLARATION EXHIBIT 7 – PART 2 OF 2

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Project No. VIP Experiment No. Date 6/12/89

Subject VICRYL IMPROVEMENT PROGRAM

Purpose SUMMARY OF PHASE I WORK

OBJECTIVE: TO IMPROVE CURRENT VICRYL BRAID IN TERMS OF HAND, STRENGTH OR BIOLOGICALS. THREE INDEPENDENT MODULES WERE EVALUATED: 1) FIBER CHEMISTRY-PROCESSING FOR IMPROVED TENACITY/BSR 2) YARN BUNDLE COHESIVENESS AND 3) BRAID RECONSTRUCTION

FIBER CHEM - PROCESSING

OBJ: EVALUATE THE PERFORMANCE (PHYSICAL PROPS, SUBJECTIVE HAND, BIOLOGICALS) OF BRAIDS PRODUCED WITH EXPERIMENTAL YARN FROM FIBER EXTRUSION DEPT (DR. MENEZES), WHICH VARIED IN CHEMISTRY AND PROCESSING CONDITIONS FROM CURRENT VICRYL.

EXPERIMENT

SUMMARY: THREE EXPERIMENTAL YARNS WERE EVALUATED: (1) ~~97~~ 96 PGA/3 PLA, (2) 90/10 HIGH TENACITY PROCESS AND (3) 90/10 HIGH IV STANDARD PROCESS. THE PRIMARY OBJECTIVE OF (1) + (2) WERE IMPROVED BRAID STRENGTH (10-20) ~~WERE~~ - IMPROVED BIOLOGICALS, AND ONLY IMPROVED BIOLOGICALS FOR (3).

ALL 3 YARN MATERIALS WERE PROCESSED PER VICRYL 2-0 SPECIFICATIONS THROUGH BRAIDING, SCOURING, HOT-STRETCHING AND ANNEALING. ANNEALED BRAID WAS COATED WITH BOTH STANDARD CALCIUM STEARATE AND GLYCOLIDE CAPROLACTONE COMPOSITIONS. COATED BRAIDS WERE EO STERILIZED. BRAIDS WERE CHARACTERIZED FOR PHYSICAL PROPS AT ALL IN-PROCESS STAGES AND FOR SUBJECTIVE HAND AFTER ANNEALING + STERILIZATION STEPS.

RESULTS:

BRAID PHYSICAL PROPERTY DATA FOR ALL 3 MATERIALS AND CONTROLS THROUGH ANNEALING, COATING AND STERIL ARE GIVEN IN FOLLOWING TABLE

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Subject Summary of Phase I

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Results of Fiber Chem - Process Module

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VICRYL IMPROVEMENT PROGRAM
BRAID PHYSICAL PROPERTIES
FIBER CHEMISTRY/PROCESSING MODULE

SIZE DESCRIPTION	PROCESS STAGE	LAB ID	DIAM (MILS)	TENSL (LBS)	INTRIN TENSL (KSI)	KNOT TENSL (LBS)	INTRIN KNOT TENS (KSI)	KNOT ELONG CONV (%)		SUBJ HAND 1:POOR 5:EXCL
2-0 97/3 PGA/PLA YARN	AN	A97-AN	12.88	17.92	137.5	10.05	77.2	56	16.48	3.5
2-0 97/3 PGA/PLA YARN	GC-ST	A97-G-S	13.78	18.45	123.7	10.19	68.4	53	19.57	0.0
2-0 90/10 HIGH IV,STD PROC.	AN	AHIV-AN	13.90	15.39	101.4	9.01	59.5	59	14.57	2.8
2-0 90/10 HIGH TENAC PROC	AN	AHT-AN	13.57	17.28	119.5	9.57	66.2	55	18.38	2.3
2-0 90/10 HIGH TENAC PROC	GC-ST	AHT-G-S	13.70	15.45	104.8	9.38	63.6	61	19.24	0.0
2-0 CONTROL (16x3, 56d)	AN	J07	13.52	15.09	105.1	8.88	61.9	59	14.76	3.0
2-0 CONTROL (16x3, 56d)	CaS	J09	13.28	15.37	110.9	9.86	71.1	64	19.20	3.0
2-0 CONTROL (16x3, 56d)	GlC	J10	12.94	15.42	117.3	9.40	71.4	61	16.06	4.4
2-0 CORNELIA PROC AVE	AN	ZZ7	12.96	15.32	116.2	8.98	68.1	59	17.16	0.0
2-0 CORNELIA PROC AVE	CaS	ZZ8	12.99	14.62	110.3	7.98	60.2	55	17.40	0.0

THE 97/3 DEMONSTRATED SIGNIFICANTLY IMPROVED TENSILE (18% INCR) AND KNOT STR (13% INCR) OVER PROCESS AVES. THE 90/10 HIGH TENACITY PROCESS DEMONSTRATED MARGINALLY IMPROVED TENSILE (3%) AND MARGINALLY INFERIOR KNOT VS PROCESS AVES. THE 90/10 HIGH IV DEMONSTRATED SIGNIFICANTLY INFERIOR PHYSICALS.

THE SUBJECTIVE HAND EVALUATION OF POST-ANNEALED BRAIDS IS SHOWN IN FIGURE THE LAST COLUMN OF THE ABOVE TABLE. CONTROLS WERE DEFINED A 3 RATING AND EXPERIMENTAL BRAIDS RANKED 1 (POOR) TO 5 (GOOD)

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ALLOWABILITY. A SLIGHT PREFERENCE WAS SHOWN FOR THE 97/3 OVER THE 2-0 CONTROL OVER THE HIGH TENACITY 90/10. THE HAND OF ALL THREE DETERIORATED SIGNIFICANTLY AFTER STERILIZATION.

CONCLUSIONS:

THE 97/3 DEMONSTRATED SIGNIFICANTLY IMPROVED PHYSICAL PROPS AND POTENTIALLY MINOR IMPROVEMENTS IN HAND AND SHOULD BE PURSUED FURTHER. THE 90/10 HT SHOULD WARRANT COVER PRIORITY.

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YARN BUNDLE COHESIVENESS

OBJECTIVE:
TO EVALUATE THE EFFECT OF YARN TWIST ON: 1) BRAID INTRINSIC SMOOTHNESS + PLIABILITY, 2) GENERAL BRAID QUALITY AND 3) BRAID PHYSICAL AND BIOLOGICAL PROPERTIES.

EXPERIMENTAL SUMMARY:
TWO YARN TWIST LEVELS AND ONE NEW YARN LUBRICANT WERE EVALUATED ON SIZE 2-0 VICRYL (CONSTRUCTION: 16x3, 56 den). THE TWIST LEVELS WERE 3.0 AND 6.0 TM (OR 3.0 TPI AND 6.1 TPI). THE PROPOSED FUNCTION OF THE TWIST IS TO INCREASE YARN BUNDLE COHESIVENESS (ROUNDER, TIGHTER MORE UNIFORM YARN BUNDLE) WHICH COULD TRANSLATE INTO A SMOOTHER, MORE UNIFORM BRAID. THE NEW YARN LUBRICANT, STANTEX 5260 (HENKEL CORP, CHARLOTTE NC), WAS APPLIED POST-EXTRUSION TO THE 56 den YARN WHICH WAS TWISTED TO 3.0 TPI OR A RATIO TWO-FOR-ONE TWISTER. SINCE THE STANTEX LUBRICANT WAS BELIEVED TO BE MUCH

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LESS VISCOUS THAN THE CURRENT CMS/MINERAL OIL, IT WAS ANTICIPATED THAT THE TWISTED YARN WOULD BE LESS RIBBON-LIKE (WHICH CONTRIBUTES TO ROUGHNESS).

OTHER THAN TWIST AND LUBRICANT CONSIDERATIONS, THE EXPERIM. & CONTROL BRAIDS WERE PROCESSED PER THE 2-0 VICRYL SPEC. COATED BRAIDS WERE PROCESSED W/ CA STEARATE AND GLYC. CAPRAL. BRAIDS WERE CHARACTERIZED AT ALL IN-PROCESS STAGES & FOR SUBJECTIVE PROPS AFTER COATING.

RESULTS:
PHYSICAL PROPERTY DATA FOR THE YBL BRAIDS ARE GIVEN IN THE FOLLOWING TABLE:

VICRYL IMPROVEMENT MODULE
BRAID PHYSICAL PROPERTIES
YARN BUNDLE COHESIVENESS MODULE

SIZE DESCRIPTION	PROCESS STAGE	LAB ID	DIAM (MILS)	TENSL (LBS)	INTRIN TENSL (KSI)	KNOT TENSL (LBS)	INTRIN KNOT TENS (KSI)	KNOT CONV (%)	ELONG (%)	SUBJ HAND 1:POOR 5:EXCL
2-0 3 TM TWIST	AN	B26	13.64	15.60	106.8	9.23	63.2	59	16.51	3.6
2-0 3 TM TWIST	CaS	B28	13.60	15.40	105.7	8.50	58.5	55	18.54	2.5
2-0 3 TM TWIST	GlC	B29	12.94	14.89	111.4	9.31	70.8	63	15.41	3.6
2-0 6 TM TWIST	AN	B43	13.86	14.78	98.0	9.37	62.1	63	15.75	3.0
2-0 6 TM TWIST	CaS	B45	13.72	15.38	104.0	8.16	55.2	53	18.14	3.3
2-0 6 TM TWIST	GlC	B46	13.04	14.32	104.6	8.37	62.9	58	16.47	4.3
2-0 STANTEX LUB/ 3 TM	AN	B09	13.36	13.02	92.8	8.53	61.0	66	16.48	1.8
2-0 CONTROL (16x3, 56d)	AN	J07	13.52	15.09	105.1	8.88	61.9	59	14.76	3.0
2-0 CONTROL (16x3, 56d)	CaS	J09	13.28	15.37	110.9	9.86	71.1	64	19.20	3.0
2-0 CONTROL (16x3, 56d)	GlC	J10	12.94	15.42	117.3	9.40	71.4	61	16.06	4.4
2-0 CORNELIA PROC AVE	AN	ZZ7	12.96	15.32	116.2	8.98	68.1	59	17.16	0.0
2-0 CORNELIA PROC AVE	CaS	ZZ8	12.99	14.62	110.3	7.98	60.2	55	17.40	0.0

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Purpose CONTINUED

TENSILE STRENGTHS WERE 7-10% LOWER FOR THE 3 + 6 TM MATERIALS VS. CONTROLS, ALTHOUGH KNOTS WERE STATISICALLY EQUIVALENT. ONLY A MARGINAL + INCONSISTENT IMPROVEMENT IN HAND WAS OBSERVED IN ANNEALED AND COATED MATERIALS FOR THE 3+6 TM SAMPLES, WITH A SLIGHT. POOREN HAND OBSERVED FOR THE 3 TM STANTEX SAMPLE.

THE EFFECT OF YARN TWIST ON VARIABILITY OF YARN TENACITY IS PRESENTED IN TABLE FORM:

VIP BUNDLE COHESIVENESS: YARN PROPERTIES (DYED 56d)

Lot #	Twist Tm	Lubric	Tenacity gpd	Tenacity %CV	Elongation %	Elongation %CV
XC3373	0	GMS/Min	5.86	5.22	19.99	5.02
XC3373	3	GMS/Min	5.76	7.29	22.26	6.02
XC3373	6	GMS/Min	6.03	8.43	21.91	3.53
USA-022	3	Stantex	5.78	3.72	25.38	5.83
88 Prod Avg.	0	GMS/Min	6.45	2.49	24.69	3.11

MS

ALTHOUGH LOT VARIABILITY IS IMPOSSIBLE TO ACCOUNT FOR IN SUCH A SMALL SAMPLING (30 PULLS ON STATIMAT), IT APPEARS THAT THE INTRODUCTION OF TWIST INCREASES YARN VARIABILITY. IT SHOULD BE NOTED THAT W TWIST WK. YARN FAILURE ELONGATION BY 2-3% FOR THE 3 + 6 TM SAMPLES. NO CONCLUSIONS COULD BE DRAWN ON BROKEN FILAMENT MANAGEMENT BY TWIST. 12 DAY IN VITRO RESULTS WERE AS FOLLOWS:

	IN VITRO BREAKING STR (LBS)	% RETENTION
2-0 CONTROL	6.51	41.7
3 TM TWIST	8.58	55.0
6 TM-TWIST	8.28	56.0

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THE NATURE OF THIS IMPROVED BIOLOGICAL PERFORMANCE MAY BE THE RECOADING OF BRAID FILAMENTS DUE TO THE TWISTED STRUCTURE, OR MAY SIMPLY BE AN ARTIFACT OF YARN / PROCESS VARIABILITY.

RECOMM.
PURSUE ON LOW PRIORITY FOR HAND IMPROVEMENT, BUT UNDERSTAND EFFECTS ON BSR + BROKEN FILAMENTS.

BRAID RECONSTRUCTION MODULE (MEDIUM SIZES)

OBJECTIVE:
TO DETERMINE WHETHER HAND IMPROVEMENTS COULD BE REALIZED BY CHANGES IN BRAID CONSTRUCTION IN MODEL SIZES 2-0 AND 1-0 VICRYL. THE PRIMARY FOCUS WAS ON UTILIZATION OF FINER DENIER SHEATH YARNS IN 24 + 16 CARRIER BRAID-ON-BRAID CONSTRUCTIONS TO FAVORABLY IMPACT SMOOTHNESS ON BRAID PROFILE.

EQUIPMENT/EXPERIMENT SUMMARY:
MAENA 24, 28, AND 32 CARRIER BRAIDERS + 16 CAR NE. BUTT WERE UTILIZED TO PRODUCE VICRYL BRAIDS IN THE 2-0 TO 1 SIZE RANGE. (NOTE: THE 28 AND 32 CARRIER CONSTRUCTS WERE FOUND TO BE FLAT AND HENCE ABANDONED). 24 CARRIER CONSTRUCTIONS WERE PRODUCED UTILIZING 14, 28, AND 40 DEN SHEATH YARNS; CORE CONSTRUCTIONS INCLUDED NON-TWISTED AND TWISTED YARN CONSTRUCTIONS, AND BRAIDED CORES SIZES 2-0, 3-0, 4-0. 16 CARR. BRAIDS WERE PRODUCED WITH 40 + 52 DEN SHEATH YARNS + 3-0 BRAIDED CORES.

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Purpose Continued

ALL UTILIZED YARNS WERE STANDARD VICRYL 90/10 PROCESSED. OTHER THAN BRAIDING CONSIDERATIONS, THE MATERIALS WERE PROCESSED PER VICRYL SPECS. SAMPLES WERE COATED + CHARACTERIZED AS OTHER ~~RESULTS~~ VIP SAMPLES AND SURFACE PROFILOMETRY / MICROSCOPIC ANALYSIS.

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RESULTS:

ALL ATTEMPTS TO UTILIZE 24 CARRIER CONSTRUCTIONS WITH TWISTED OR NON-TWISTED YARN ASSEMBLIES ~~CORE~~ BRAID CORES RESULTED IN FLAT BRAIDS, ALTHOUGH OUTSTANDING SMOOTHNESS AND PLIABILITY WERE OBSERVED. (THE PHYSICAL PROPERTIES OF LAB ID E25b WITH A TWISTED CORE ARE INCLUDED IN THE RESULTS TABLE FOR COMPARISON PURPOSES). THE FLATTENING ISSUE WAS OVERCOME WHILE PRESERVING THE SMOOTHNESS GAINS, BY THE INCORPORATION OF A BRAIDED CORE OR "BRAID-ON-BRAID" CONSTRUCTION. THE BRAIDED CORE WITHIN THE SHEATH TUBE OR LINER OFFERS A HIGHER RESISTANCE TO TRANSVERSE COMPRESSION RELATIVE TO THE TWISTED YARN ASSEMBLY SO THAT FLATTENING EVEN IN THE 24 CARRIER CONSTRUCT. WAS MINIMIZED.

PHYSICAL PROPS OF THE MEDIUM SIZE RECONSTRUCTIONS ARE GIVEN IN THE FOLLOWING TABLE. D25 f COMPARED FAVORABLY WITH THE CONTROL 2-0 IN SUBJECTIVE HAND AND POSSESSED STATIST. EQUIV. PHYSICALS. THE R_z PEAK-TO-VALLEY DISTANCE MEASURED BY SURFACE PROFILOMETRY DEMONSTRATED A 30-35% REDUCTION IN BRAID PROFILE FOR THE 24 CARRIER CONSTRUCTIONS VS CONTROLS, AND VALUES COMPARABLE TO TYPICAL 2-0.

PHYSICAL PROPS FOR 1-0 RECONSTRUCT. ARE ALSO GIVEN IN FOLLOWING TABLE. D25h EXHIBITED 10-15% HIGHER INITIAL TENSILE AND MARGINALLY HIGHER KNOT

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Subject Summary of PHASE I

Purpose CONTINUED.

USL CONTROLS AND PERFORMED SIGNIFICANTLY BETTER IN THE SUBJ. HAND EVALUATION. ABSOLUTE AND NORMALIZED Rz DEMONSTRATE 30% REDUCTION IN BRAID PROFILE.

VICRYL IMPROVEMENT PROGRAM
BRAID PHYSICAL PROPERTIES
MEDIUM SIZE BRAID RECONSTRUCTION MODULE

SIZE DESCRIPTION	PROCESS STAGE	LAB ID	DIAM (MILS)	TENSL (LBS)	INTRIN TENSL (KSI)	KNOT TENSL (LBS)	INTRIN KNOT TENS (KSI)	KNOT CONV (%)	ELONG (%)	SUBJ HAND 1:POOR 5:EXCL	Rz/r (PEAK -VALL /RAD)
2-0 24 CARRx28d,3-0 BRD COR AN	AN	D25f	14.88	19.72	113.4	10.42	60.0	53	16.29	4.4	0.101
2-0 24 CARRx28d,3-0 BRD COR GC-ST	GC-ST	D32f	14.62	18.07	107.7	10.52	63.4	58	19.93	0.0	0.106
2-0 24 CARRx28d,4-0 BRD COR AN	AN	D25i	14.12	15.98	102.1	8.72	55.7	55	15.68	4.5	0.105
2-0 16 CARRx40d,3-0 BRD COR AN	AN	M25b	14.60	18.60	111.1	11.27	67.4	61	17.44	0.0	0.082
2-0 CONTROL (16x3, 56d)	AN	J07	13.52	15.09	105.1	8.88	61.9	59	14.76	3.0	0.158
2-0 CONTROL (16x3, 56d)	CaS	J09	13.28	15.37	110.9	9.86	71.1	64	19.20	3.0	0.000
2-0 CONTROL (16x3, 56d)	GLC	J10	12.94	15.42	117.3	9.40	71.4	61	16.06	4.4	0.000
2-0 CONTROL (16x3, 56d)	GC-ST	J16	12.88	14.48	111.2	9.24	71.0	64	17.75	0.0	0.130
2-0 CORNELIA PROC AVE	AN	ZZ7	12.96	15.32	116.2	8.98	68.1	59	17.16	0.0	0.000
2-0 CORNELIA PROC AVE	CaS	ZZ8	12.99	14.62	110.3	7.98	60.2	55	17.40	0.0	0.000
1-0 24 CARRx40d,3-0 BRD COR AN	AN	D25h	16.32	24.01	114.8	13.10	62.6	55	17.64	4.5	0.081
1-0 24 CARRx40d,3-0 BRD COR CG-ST	CG-ST	D32h	16.40	21.95	103.9	13.25	61.7	60	20.25	0.0	0.000
1-0 24 CARRx28d,2-0 BRD COR AN	AN	D25e	16.76	23.24	105.1	12.92	58.6	56	16.10	4.3	0.098
1-0 16 CARRx52d,3-0 BRD COR AN	AN	M25a	15.30	21.59	117.4	11.62	65.5	61	19.02	0.0	0.092
1-0 CONTROL (16x3, 80d)	AN	K05	16.27	21.60	103.9	11.09	53.3	51	20.38	3.0	0.130
1-0 CORNELIA PROC AVE	AN	ZZ3	16.15	20.79	101.5	12.54	61.2	60	17.40	0.0	0.000
1-0 CORNELIA PROC AVE	CaS	ZZ4	15.99	20.63	102.8	11.37	56.6	55	18.95	0.0	0.000
1 24 CARRx52d,10x80d TV C AN	AN	E25b	17.54	27.83	115.1	17.30,	71.8	62	17.95	0.0	0.000

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Purpose CONTINUED

24 CARRIER BRAIDS WERE JUDGED TO HAVE SUPERIOR HAND VS. CONTROL AFTER STERILIZATION, HOWEVER THE MARGIN WAS REDUCED. DUE TO PERMANENT SETS OCCURRING DURING PACKAGING. TWO PRIMARY TYPES ~~TAPE~~ OF ROUGHNESS DEFECTS WERE OBSERVED: (1) LOCALIZED FLATTENING AT "CLOSE-UP" CROSSOVER PTS AND BEND SECTIONS, AND (2) PERM SET KINKS AT CROSSOVER POINTS. THE DEFECTS ARE SHOWN SCHEMATICALLY BELOW WITH WORST CASE DIMENSIONS:

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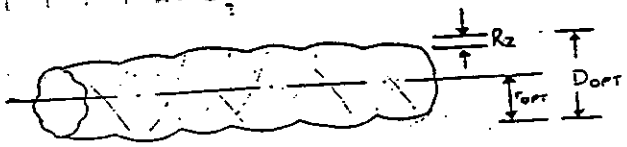

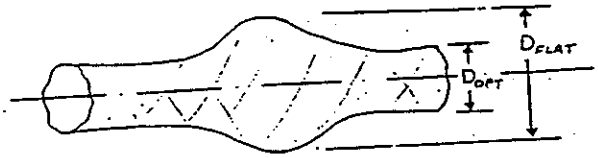

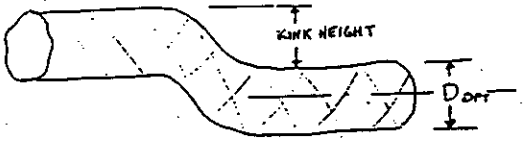

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BRAID PROFILE ANALYSIS AFTER STERILIZATION
SIZE 2-0 CONTROL AND 24 CARRIER BRAID-ON-BRAID
WORST CASE MEASUREMENTS (MILS)

Lab ID	Diam (USP)	Diam (Optic)	Rz Anneal	Rz Coated Sterile	Diam. Flat Before Tug-Down	Diam. Flat After Tug-Down	Perm. Set Kink Before Tug-Down	Perm. Set Kink After Tug-Down
032f[1]	14.88	17.5	0.75	0.78	28.6	23.9	13	4.7
J16[2]	12.88	16.6	1.05	0.84	25.7	21.2	14	5.5

1 Construction (S=24x28d C=3-0 Braid)
2 Construction (S=16x56d C=3x56d)

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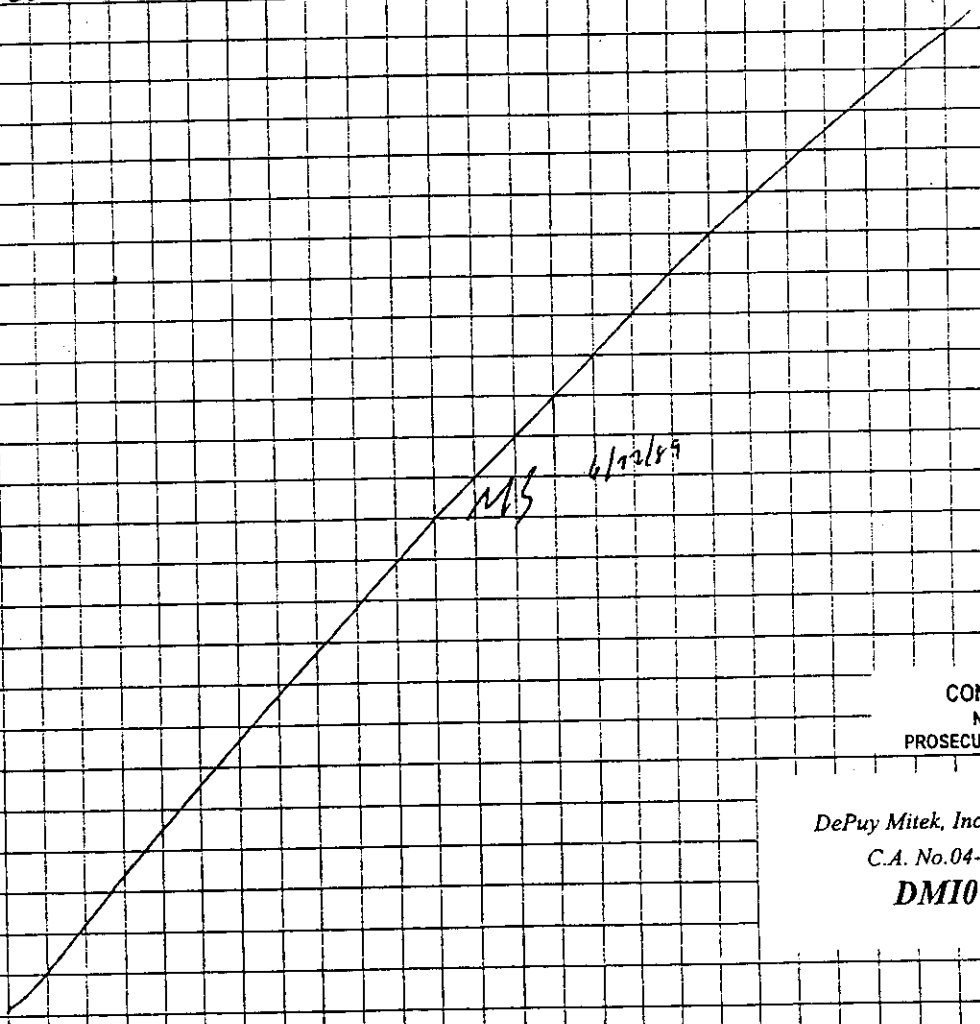
Purpose CONTINUED

THE MATERIALS WERE FIRST TUGGED DOWN ON A-INSTRON (3.5 LBS FOR 2 SECS, 10 in/min XHS) TO REMOVE INITIAL PACKAGE SET

RECOMMENDATIONS:

THE 24 CARRIER BRAID ALLOWS THE USAGE OF FINER DENIER YARNS WHICH TRANSLATE INTO A SMOOTHER BRAID HOWEVER, WITHOUT CONCURRENT GAINS IN PACKAGING A LARGE FRACTION OF THE POTENTIAL IS LOST.



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Purpose CONTINUED

16 CARRIER BRAID-ON-BRAID CONSTRUCTIONS DEMONSTRATED SIMILAR SUBJECTIVE SMOOTHNESS AND PROFILOMETER SMOOTHNESS TO THE 24 CARRIER OF COMPARABLE SHEATH DENIER. A PENALTY IN STIFFNESS APPEARS APPARENT W/ THE 16 CARRIER DUE TO HIGHER CORE / SHEATH VOLUME FRACTIONS.

	R2/r	Comments
Control - 16x3	0.158	J07
16x40d, 3-0 core	0.082	M25b
24x40d, 3-0 core	0.081	D25h

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Project No. SILK Experiment No. Date 6/19/89
Subject SILK DEGUMMING + EFFECT ON UNSILEINING
Purpose DETERMINE CAUSE OF MANUF PROBLEMS

(2x2 1315)

BACKGROUND:
TWO LOTS OF RAW AND DEGUMMED SILK PROVIDED BY MR J.M KRAMER OF CORNELIA WERE ANALYZED DUE TO DIFFERENCES IN PROCESSABILITY IN UNSILEINING AFTER DEGUM SCOUR. LOT 88-24D CTN-4 RAN WITHOUT INCIDENT, WHEREAS LOT 88-24A CTN 17 RAN WITH A HIGH FREQ OF YARN BREAKS DURING UNSILEINING. THE RESULTS OF THE CHARACTERIZATION OF THE TWO LOTS ARE AS FOLLOWS (DEGUMMED):

PROPERTY	GOOD YARN 88-24D CTN-4	POOR YARN 88-24A CTN 17
TENSILE STRENGTH (Gms)	191.4 ± 35.9	188.7 ± 38.1
TWIST (TPI) (PLY)	16.9 ± 0.8	16.3 ± 1.1
DENIER	43	45
RESIDUAL GUM	VERY LOW LEVEL	MODERATE LEVEL

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DMI002653

DISCUSSION:
TENSILE, TWIST + DENIER WERE STATISTIC. EQUIVALENT. HOWEVER, DIFFERENCES IN RESIDUAL GUM LEVEL (BY OPTICAL MICROSCOPY) WERE SIGNIFICANT. ALTHOUGH MAJORITY OF GUM WERE REMOVED IN BOTH CASES WHEN COMPARED TO RAW SILK, HIGHER LOCAL LEVELS WERE PRESENT IN THE POOR RUNNING YARN. IT IS PLAUSIBLE THAT THE TACKINESS OF THE RESIDUAL GUM LEVEL PREVENTS THE SKEIN FROM UNWINDING CLEANLY RESULTING IN YARN BREAKS.

Investigator [signature] Date 6/19/89
Witness [illegible] Date 3-15-90

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Book No. 2175

Project No. VIP Experiment No. Date 7/26/89

Subject BRAID STRESS - STRAIN PROPS

Purpose EVALUATE DIFFERENCES IN DEXON, VICRYL, PGA, 97/3

PROCEDURE:

THE BRAID STRESS-STRAIN BEHAVIOR WAS DETERMINED FOR 4 SIZE 2-0 BRAIDS: (1) VICRYL 90/10, (2) DEXON, (3) 100% PGA PROCESSED PER VICRYL SPEC, (4) 97/3 PGA/PLA PROCESSED PER VICRYL SPEC. ALL BRAIDS WERE STERILE AND PACKAGED, HOWEVER WHERE TUGGED DOWN BEFORE TESTING USING AN INSTRON (3.5 LBS - 2 SECS, 10"/MIN - XHS). THE MATERIALS WERE TESTED USING THE FOLLOWING CONDITIONS: XHD: 300 mm/min, CS: 300 mm/min, GL 254 mm, ASL 10 LB, GRIPS 40PSI, FACES: RUBBER.

RESULTS

PROPERTY	VICRYL	DEXON	97/3	100% PLA
TENSILE STREN. (LB)	6.61	6.82	8.23	7.35
ULT ELONG (%)	19.00	~~29.13~~ 30.16	19.17	15.8
INIT MODULUS (GM/DEN)	67.45	55.80	74.70	77.42

MS 7/26/89

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C.A. No.04-12457 PBS
DMI002654

Investigator [signature] Date 7/26/89

Witness Carolyn Britt Date 3-15-90

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Book No. 175

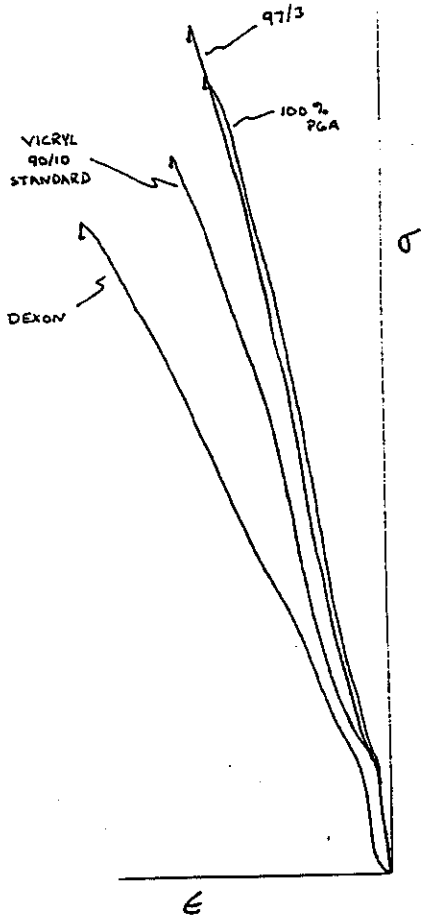
Project No. VIP Experiment No. Date 9/26/89

Subject BRAID STRESS-STRAIN CURVES

Purpose CONTINUED

THE FOLLOWING ARE REPRESENTATIVE CURVES:

σ-ε CURVES OF STERILE 2-0 BRAID



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DMI002655

DISCUSSION:

THE DEXON BRAID POSSESSES THE LOWEST INIT MODULUS (MOST LIKELY REFLECTING AN ORIENTATION EFFECT) AND HIGHEST ELONGATION. ALSO, THE DEXON BRAID POSSESSES AN INITIAL REGION OF σ-ε TYPICAL OF BRAID DEFORMATION. THESE ATTRIBUTES MAY CONTRIBUTE TO THE HAND OF DEXON VS VICRYL.

Investigator [signature] Date 7/26/89

Witness Ginny Land Britt Date 3-15-90

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Book No. 2175

Project No. EI Experiment No. Date 8/11/89

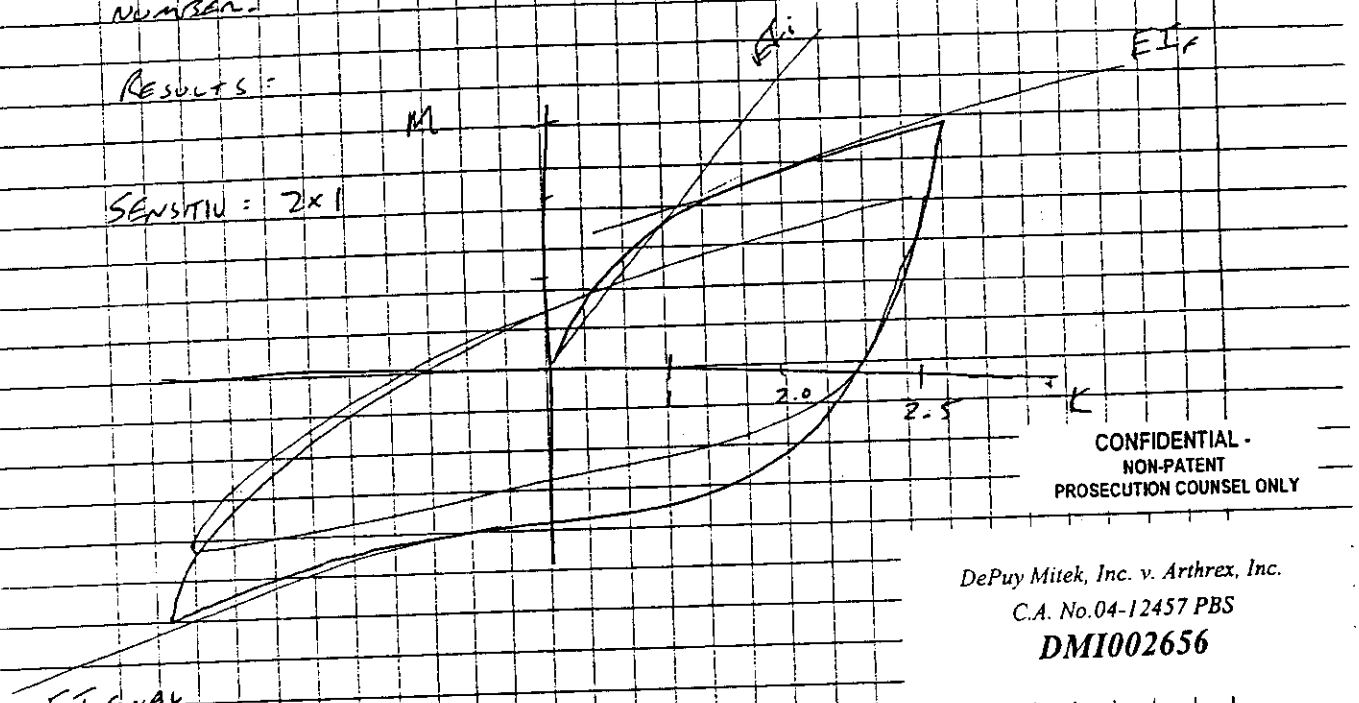
Subject VICRYL 2-0 DYED - OFF-BRAIDER

Purpose DETERMINE INITIAL + FINAL BENDING RIGIDITY

BACKGROUND / PROCEDURE:

VICRYL 3-0 VIOLET OFF-BRAIDER WAS TESTED ON THE KAWABATA PURE BENDING TESTER. STRANDS WERE MOUNTED ON PRE-CUT TABS WITH DOUBLE-STICK TAPE ON GLUE-STICK AND WOUND ON THE RACK WINDER. APPROX 50 STRANDS WERE WOUND + TRIMMED DOWN TO REQUIRED NUMBER.

RESULTS:



SENSITIV: 2x1

EI FINAL

EI INITIAL

SAMPLE (1)	K	M
	0	0
	0.2	.09
	0.4	.12
	0.6	.14
	0.8	.155
	1.0	.168

N = 38

SLOPE: 0.151

$EI_i = \frac{0.151 \times 20}{38} = 7.94 \times 10^{-2}$ gm-cm²/strand

EI FINAL	K	M
FORWARD:	1	.155
	3	.292

SLOPE: 0.0685

BACKWARD:	-1	-.118
	-3	-.232

SLOPE: 0.057

AVE = 0.062

$EI_{final} = \frac{(0.063) \times 20}{38} = 3.3 \times 10^{-2}$ gm-cm²/strand

Investigator [signature] Date 8/11/89

Witness Crawford Britt Date 3-15-90

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Book No. 175

Project No. EI Experiment No. Date 8/11/89

Subject NICRO 2-0 BRAID

Purpose EI initial + EI final

SAMPLE (2)

n = 39

	EI_i K	EI_i M
	0	0
	0.2	0.125
	0.4	0.162
	0.6	0.185
	0.8	0.202
	1.0	0.220

SLOPE = 0.193

$EI_i = \frac{(0.193)(20)}{39}$

$= 9.90 \times 10^{-2}$

EI_f	K	M
FORWD	1.0	.192
	3.0	.378

SLOPE = 0.093

	K	M
BKWD	-1	-.120
	-3	-.255

SLOPE = 0.068

AVE SLOPE = 0.080

$EI_f = \frac{(0.080)(20)}{39} = 4.12 \times 10^{-2}$

SAMPLE (3)

n = 39

	EI_i	K	M
1		0	0
2		.2	.118
3		.4	.136
4		.6	.155
5		.8	.166
6		1.0	.180

SLOPE = 0.152

$EI_i = (0.152)(20)/39$

$= 7.79 \times 10^{-2}$

E_f	K	M
1F	1	.156
2F	3	.275
SLOPE		0.059
1B	-1	-.107
2B	-3	-.268
SLOPE =		0.0505

AVE SLOPE = 0.055

$EI_f = (0.055)(20)/39$

$= 2.82 \times 10^{-2}$

SAMPLE (4)

n = 39

	EI_i	K	M
1		0	0
2		.2	.142
3		.4	.175
4		.6	.20
5		.8	.215
6		1.0	.232

SLOPE 0.20

$EI_i = \frac{(0.20)\,20}{39} = 10.26 \times 10^{-2}$

E_f	K	M
1F	1	.220
2F	3	.385
SLOPE		0.0825
1B	-1	-.11
2B	-3	-.242
SLOPE		0.066

AVE SLOPE 0.074

$EI_f = (0.074)\frac{20}{39} = 3.81 \times 10^{-2}$

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DMI002657

Investigator [signature] Date 8/11/89

Witness Ronald Britt Date 3-15-90

Project No. EI Experiment No. Date 8/11/89

Subject Ultra 2-0 BRAID OFF-BRAID

Purpose EI_i ; EI_f

Sample (5)	EI_i K	M	EI_f K	M
	1 0	0	1F	+1 .210
n=39	2 .2	.125	2F	+3 .390
	3 .4	.155	SLOPE-F	0.090
	4 .6	.175	1B	-1 -.120
	5 .8	.190	2B	-3 -.255
	6 1.0	.210	SLOPE-B	0.0675
	SLOPE = 0.181		SLOPE-AVE	0.07875

$EI_i = \frac{(0.181)(20)}{39} = 9.28 \times 10^{-2}$ $EI_f = \frac{(0.0787)(20)}{39} = 4.04 \times 10^{-2}$

Sample (6)	EI_i K	M	EI_f K	M
n=39	1 0	0	1F	+1 .180
	2 0.2	.132	2F	+3 .316
	3 .4	.150	SLOPE-F	0.068
	4 .6	.175	1B	-1 -.107
	5 .8	.190	2B	-3 -.223
	6 1.0	.202	SLOPE-B	0.058
	SLOPE = 0.173		SLOPE-AVE	0.063

$EI_i = \frac{(0.173)(20)}{39} = 8.88 \times 10^{-2}$ $EI_f = \frac{(0.063)(20)}{39} = 3.23 \times 10^{-2}$

Sample (7)	EI_i K	M	EI_f K	M
n=39	1 0	0	1F	+1 .15
	2 0.2	.122	2F	+3 .305
	3 .4	.136	SLOPE-F	0.0775
	4 .6	.132	1B	-1 -.16
	5 .8	.146	2B	-3 -.295
	6 1.0	.161	SLOPE B	0.675
	SLOPE = 0.126		SLOPE-AVE	0.07125 0.0725

$EI_i = \frac{(.126)(20)}{39} = 6.46 \times 10^{-2}$ $EI_f = \frac{(0.0725)(20)}{39} = 3.72 \times 10^{-2}$

Investigator [signature] Date 8/11/89

Witness Craig Britt Date 3-15-90

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Book No. 2175

Project No. EI Experiment No. Date 8/11/89

Subject VICRYL 2-0 BRAID - OFF BRAIDER

Purpose CONTINUED

SAMPLE (8)	EI	K	M	EI_F	K	M
n=39	1	0	0	1F	1	.185
	2	0.2	.117	2F	3	.350
	3	0.4	.142	SLOPE-F	0.0825	
	4	0.6	.170	1B	-1	-.090
	5	0.8	.185	2B	-3	-.205
	6	1.0	.195	SLOPE-B	0.0625	
	SLOPE = 0.172			SLOPE-AVE	0.0725	

$EI_i = \frac{(0.172)(20)}{39} = 8.82 \times 10^{-2}$ $EI_F = \frac{(0.0725)(20)}{39} = 3.71 \times 10^{-2}$

Results Summary

Sample	EI_i	EI_F
1	7.94	3.30
2	9.90	4.12
3	7.79	2.82
4	10.26	3.81
5	9.28	4.04
6	8.88	3.23
7	6.46	3.72
8	8.82×10^{-2}	3.72×10^{-2}
Ave	8.67×10^{-2}	3.60×10^{-2} gm·cm²/strand
SD n-1	1.23	0.44
% CV	14.2%	12.2%

Investigator

Witness Crawford Britt

Date 8/11/89

Date 3-15-90

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Book No.

2175

Project No. 16212 Experiment No. Date 9/15/89

Subject SURFACE FLUORINATION OF VICRYL SUTURE

Purpose EVALUATION EFFECT ON HAND AND KNOT TIE-DOWN

SIZE 2-0 VIOLET

BACKGROUND: SAMPLES OF VICRYL BRAID LOT # A3801 (CONNELLA) AFTER SCOURING WERE PROCESSED BY TEKMAT CORPORATION OF ASHLAND MASS. THREE PROCESS CONDITIONS OF THE FLUORINE SURFACE PLASMA TECHNIQUE WERE PERFORMED BY TEKMAT AND RETURNED. THE SAMPLES HAVE BEEN LABELED:

A3801 - 0B - T1 (TREATMENT 1)
A3801 - 0B - T2 " 2
A3801 - 0B - T3 " 3
A3801 - 0B - C CONTROL - NO TREATMENT

PROCEDURE & RESULTS:

SAMPLES WERE EVALUATED FOR HAND & TIE-DOWN BY MGS. THE SAMPLES T1, T2 T3 WERE ALL WORSE THAN THE CONTROL FOR HAND PRIMARILY DUE TO A GROSS UNDULATION OR ROUGHNESS IN THE BRAID. IT APPEARS THAT THE BRAIDS WERE SUBJECTED TO A THERMAL TREATMENT W/O TENSION AND THAT THE CORE RELAXATION ALLOWED DIFFERENTIAL SHRINKAGE IN THE BRAID. SAMPLE 3 HAD THE MOST PRONOUNCED EFFECT, SAMPLES 1 AND 2 WERE COMPARABLE & SIGNIFICANTLY WORSE THAN THE CONTROL IN TERMS OF KNOT TIE-DOWN, SAMPLE 3 WAS SLIGHTLY BETTER THAN THE CONTROL — A STABLE SLIDING ACTION WAS OBTAINABLE FOR EARLY THROWS, AS OPPOSED TO THE DRAMATIC STILL-SLIP ACTION OF T1, T2 AND THE CONTROL. EVEN THOUGH, T3 WAS STILL SIGNIFICANTLY ROUGHER AND RASPIER THAN ~~T~~ A COATED VICRYL SUTURE IN TIE-DOWN AND WOULD MOST LIKELY NOT BE SUITABLE FOR GENERAL APPLICATION IN THE NON-COATED FORM.

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Investigator [signature] Date 9/15/89

Witness Crawford Britt Date 3-15-90

DePuy Mitek, Inc. v. Arthrex, Inc. C.A. No.04-12457 PBS DMI002660

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Book No. 175

Project No. MFE Experiment No. Date 10/19/89
Subject MICROFIBER EVALUATION
Purpose EVALUATE THE BENDING + TENSILE PROPERTIES OF FINE DPF POLYESTER YARNS VS. CONVENTIONAL DACRON YARN

MATERIALS:

		(den / # FILAMENTS)	dpf
ASAHI (JAPAN)	110/1100 PET		0.1
ASAHI	50/96 PET		0.52
DACRON (DuPont)	110/134/1ST2 PET		3.23
DACRON	55/27/1ST2 PET		2.0

PROCEDURE:

THE ABOVE 4 TYPES OF PET WERE INDIVIDUALLY BRAIDED IN 8x1 CONSTRUCTIONS USING NE BUTT BRAIDERS; CONDITIONS: 34 PICK, SH SPRING = 0.009" DIAM x 5", TEXTROL CORE TENSION 12-18 GMS). THE BRAIDS WERE THEN HOT-STRETCHED USING THE ETHIBOND HOT-PLATE AT 400°F AND 15 7 0 + 90 FPM TAKE-UP AND 8 WRAPS ON ROLL 1 AND 8 WRAPS ON ROLL 2. THE SAMPLES WERE LABELED AS FOLLOWS:

BRAID ID	YARN	
MFE-01	ASAHI 110d	/ 0.1 dpf
MFE-02	DACRON 110d	/ 3.23 dpf
MFE-03	ASAHI 50d	/ 0.52 dpf
MFE-04	DACRON 55d	/ 2.0 dpf

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RESULTS

THE FOLLOWING DIAM, TENSILE, AND KNOT STRENGTHS WERE DETERMINED:

SAMPLE	DIAM (MILS)	BREAK STR (LBS)	INTRIN TENS STR (PSI)	KNOT STR (LBS)	KNOT INTRIN (PSI)	TENSILE EF (%)
MFE-01	12.87	7.704	59,220	4.320	33,200	7.3
MFE-02	12.84	13.80	106,500	7.414	57,300	12.9
MFE-03	7.48	5.27	119,900	2.933	66,780	7.8
MFE-04	8.820	7.58	124,100	3.952	64,810	8.34

Investigator Mal Slaten Date 10/19/89
Witness Raymond Britt Date 3-15-90

DePuy Mitek, Inc. v. Arthrex, Inc.
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DMI002661

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Project No. MFE Experiment No. Date 10/19/89

Subject

Purpose CONTINUED FROM p52

THE SAME BRAIDS WERE TESTED WITH THE KAWABATA PURE BENDING TESTER FOR INITIAL AND FUNCTIONAL (2ND CYCLE) EI ($gf \cdot cm^2$/STRAND)

SAMPLE	DIAM	$EI_{STRAND,\ INITIAL}$	$EI_{STRAND,\ FUNC\ (2^{ND}\ CYCLE)}$
MFE-01	12.87	46.1×10^{-2}	15.6×10^{-2}
MFE-02	12.84	14.8×10^{-2}	
MFE-03	7.48	28.8×10^{-2}	3.03×10^{-2}
MFE-04	8.82	16.4×10^{-2}	3.09×10^{-2}

TO NORMALIZE THE ABOVE RESULTS FOR DIAMETER, THE (I_z) MOMENT OF INERTIA CAN BE CALCULED FROM THE RADIUS OF ($\pi d^4/32$) SO THAT E (COMPOSITE TENSILE & COMPRESSIVE MODULUS) CAN BE DETERMINED

DPF	SAMPLE	I_z (cm^4)	$E_{STRAND,\ INITIAL}$ (gm/cm^2)	$E_{STRAND,\ FUNCTIONAL}$ (gm/cm^2)	DIAM (cm)
0.1	MFE-01	1.11×10^{-7}	4.19×10^6	1.40×10^6	3.26×10^{-2}
3.23	MFE-02	1.11×10^{-7}	1.33×10^6		3.26×10^{-2}
0.52	MFE-03	1.25×10^{-8}	2.30×10^7	2.42×10^6	1.89×10^{-2}
2.0	MFE-04	2.47×10^{-8}	6.64×10^6	1.25×10^6	2.24×10^{-2}

DISCUSSION:

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Investigator Date 10/19/89

Witness Crawford Britt Date 3-15-90

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Project No. MFF Experiment No. Date 10/19/89
Subject MICROFIBER EVALUATION
Purpose CONT. FROM P53

INITIAL MODULUS (E) DERIVED FROM BENDING TESTS AS A FUNCTION OF DPF FOR PET

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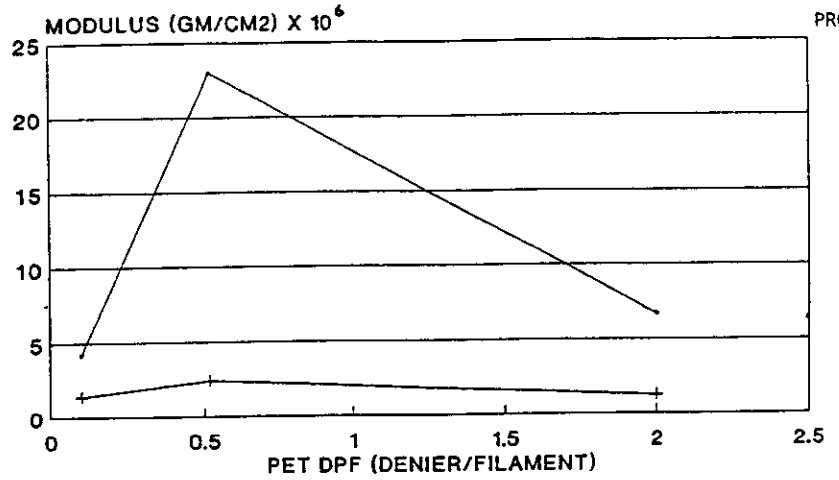

E= EI/I WHERE I= πr⁴/ 32

MS 10/19/89

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DMI002663

DISCUSSION:

PLIABILITY OR BENDING RIGIDITY IS A FUNCTION DEPENDENT ON SEVERAL FACTORS IN BRAIDED SUTURES INCLUDING: 1) FIBER MODULUS, 2) FIBER DIAMETER & SHAPE, 3) BRAID CONSTRUCTION, 4) FIBER SURFACE PROPS SUCH AS LUBRICANT TYPE, INTRINSIC SURFACE TENSION, AND 5) HOT-STRETCH CONDITIONS WHICH DETERMINE FIBER/YARN BUNDLE PACKING AND DEGREE OF MECHANICAL INTERLOCKING OR FIBER MOBILITY. FROM A SIMPLE THEORETICAL VIEWPOINT, LOWER DPF SHOULD RESULT IN LOWER EI SINCE I = πr⁴/32. HOWEVER LOWER DPF ALSO MEANS HIGHER FIBER SURFACE AREA WHICH AFFECTS FIBER/YARN PACKING, THE DEGREE OF FIBER MOBILITY AND THE CONTRIBUTION OF FIBER-FIBER INTERACTION. EVIDENTLY IN THE PRODUCTS TESTED, THE FIBER INTERACTION EFFECTS DOMINATED OVER THE FIBER FINENESS. TWO POINTS SHOULD BE NOTED: 1) THE FIBER MODULUS WAS NOT CONSTANT FOR ALL 3 SAMPLES, THE 0.5 WAS PROBABLY HIGHER THAN 0.1, AND 2) THE PRODUCTS WERE HOT-STRETCHED AT CONDITIONS OPTIMIZED FOR 2.0 DPF PRODUCT, WHICH MAY BE TOO SEVERE FOR 0.1 + 0.52 DPF FIBERS.

Investigator [signature] Date 10/19/89
Witness [illegible] Date 3-15-90

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Book No. 2175

Project No. IDEA Experiment No. Date 11/16/89

Subject EXPANDED MONOFILAMENT WITH MULTIFILAMENT PROPS

Purpose DOCUMENT CONCEPTION OF INVENTION

IDEA: A SUTURE CAN BE PRODUCED WHICH APPEARS TO BE A MONOFILAMENT EVEN AT LOW MAGNIFICATION (10X) BUT WHICH BEHAVES LIKE A MULTIFILAMENT BRAID IN TERMS OF PLIABILITY / HANDLING PROPS BY "EXPANDING" THE CONTINUUM OF POLYMER INTO A PLURALITY OF MICROFIBRILS. THIS TECHNOLOGY IS APPLIED TO PTFE IN THE FORMATION OF THE GORE SUTURE. HOWEVER, THE PTFE EMBODIMENT HAS DISADVANTAGES, MOST NOTABLY LOW STRENGTH AND KNOT SECURITY. THIS COULD BE IMPROVED UPON BY APPLYING THE TECHNOLOGY TO HIGHER STRENGTH POLYMERS, SUCH AS PE AND PP. A HIGH CRYSTALLINITY POLYMER (PREFERABLY > 55%) IS NECESSARY FOR THIS APPROACH IN ORDER TO FORM THE MICROFIBRILLAR STRUCTURE. THIS HIGH CRYSTALLINITY CAN BE MADE POSSIBLE BY THE USE OF VERY PURE HIGH MW POLYMER, AND BY CONTROLLING THE SPINNING AND ORIENTATION CONDITIONS, AS WELL AS BY A POST-ORIENTATION ANNEALING OPERATION. THE MONOFILAMENTS ARE CONVERTED INTO THE EXPANDED STRUCTURE BY A "COLD-DRAWING" OPERATION, WHERE THE FILAMENTS ARE EXTENDED BETWEEN GODETS AT A HIGH RATE AT AMBIENT OR MINIMAL THERMAL EXPOSURE. ALTERNATIVELY, A SIMILAR STRUCTURE CAN BE OBTAINED BY SOLVENT SPINNING WHERE THE SOLVENT REMOVAL RESULTS IN A PORE STRUCTURE WHICH IS THEN ORIENTED.

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Investigator [signature] Date 11/16/89

Witness Crawford Butt Date 3-15-90

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Book No. 175

Project No. CBE Experiment No. Date 12/13/89

Subject PREFERRED CONSTRUCTION FOR PTFE/PET COMPOSITE BRAID

Purpose PROPRIETARY BRAID WITH IMPROVED HANDLING PROPERTIES

BACKGROUND: (PG 26) PTFE/PET CARRIER BLENDS HAVE BEEN FOUND TO OFFER EXCEPTIONAL HANDLING PROPERTIES FOR A BRAIDED SUTURE.

CONSTRUCTION:
A CARRIER BLEND COMPOSITE BRAID IS PRODUCED USING PTFE YARNS AND PET YARNS. THE SHEATH x CORE COUNT IS 16x3. THE SHEATH CARRIER LAYOUT IS 2 PTFE, 2 PET, 2 PTFE ... WHICH INSURES A TORSIONALLY STABLE BRAID SINCE AN EQUAL # OF CARRIERS EXIST IN THE CW AND CCW DIRECTIONS. THE CORE YARNS ARE ALL PET FOR ADDED STRENGTH. THE PTFE YARNS ARE 75 den / 12 FILAMENT MANUFACTURED BY SHOWA (JAPAN), THE PET YARNS ARE 55 DEN/27 FILAMENT / TYPE 52 MANUFACTURED BY DuPONT. THE TOTAL VOLUME FRACTION OF EACH COMPONENT ARE: PTFE 52%, PET 44%.

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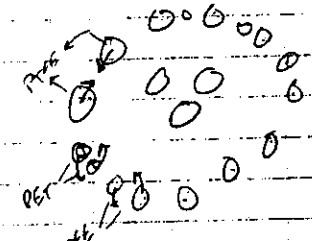
PROCESSING:
THE YARNS WERE WOUND ON BOBBINS PER STANDARD METHOS AND PLACED ON THE BRAIDER PER FIG. 1. A 0.5 oz WAS USED FOR TENSION ON THE PET YARN, NO YARN TENSION SPRING WAS USED ON THE PTFE. A 32 PICK GEAR WAS USED RESULTING IN 42 PPI. CORE TENSION WAS ADJUSTED TO 30 GMS. AFTER BRAIDING, THE SUTURE WAS SCOURED AND HOT-STRETCHED OVER A HOT-PLATE AT 400°F AND 15% STRETCH RATIO. SUBSEQUENTLY, THE SUTURE WAS PASSED THROUGH A 11 mil DIE AFTER PASSING THROUGH A FORCED AIR OVEN AT 300°F.



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DMI002665

Investigator [signature] Date 12/13/89

Witness Ronald Smith Date 3-15-90

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Book No. 2175

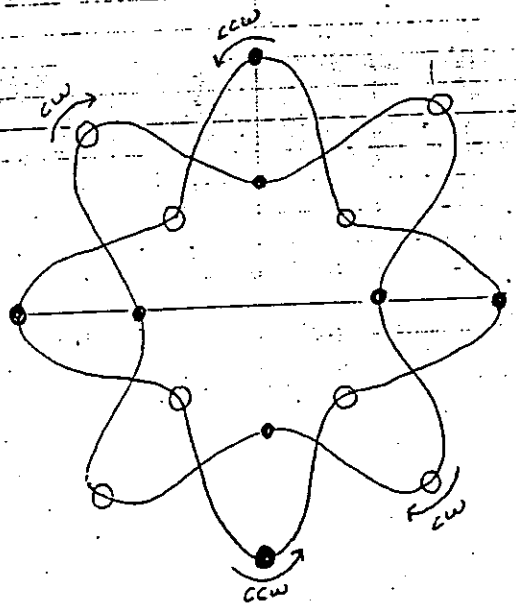
Project No. CBE Experiment No. Date 12/13/89

Subject CONTIN. FROM 2175-56

Purpose

PROPERTIES:

THE DIAMOND COMPOSITE BRAID HAD SUPERIOR HANDLING PROPERTIES RELATIVE TO SILK AND ETHIBOND, WHICH IS DEMONSTRATED QUANTITATIVELY IN FIG 2 OF THE FLEXURAL BENDING RIGIDITY RESULTS. THE INTRINSIC TENSILE AND KNOT STRENGTHS WERE 87 KSI AND 48 KSI RESPECTIVELY. THE COMPOSITE ALSO RANKED BETTER THAN THE SILK AND ETHIBOND IN KNOT TIE-DOWN, EVEN WITHOUT A COATING.



MB 12/10/89

FIG. 1. SCHEMATIC OF CARRIER LAY OUT FOR BALANCED COMPOSITE BRAID.

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Purpose

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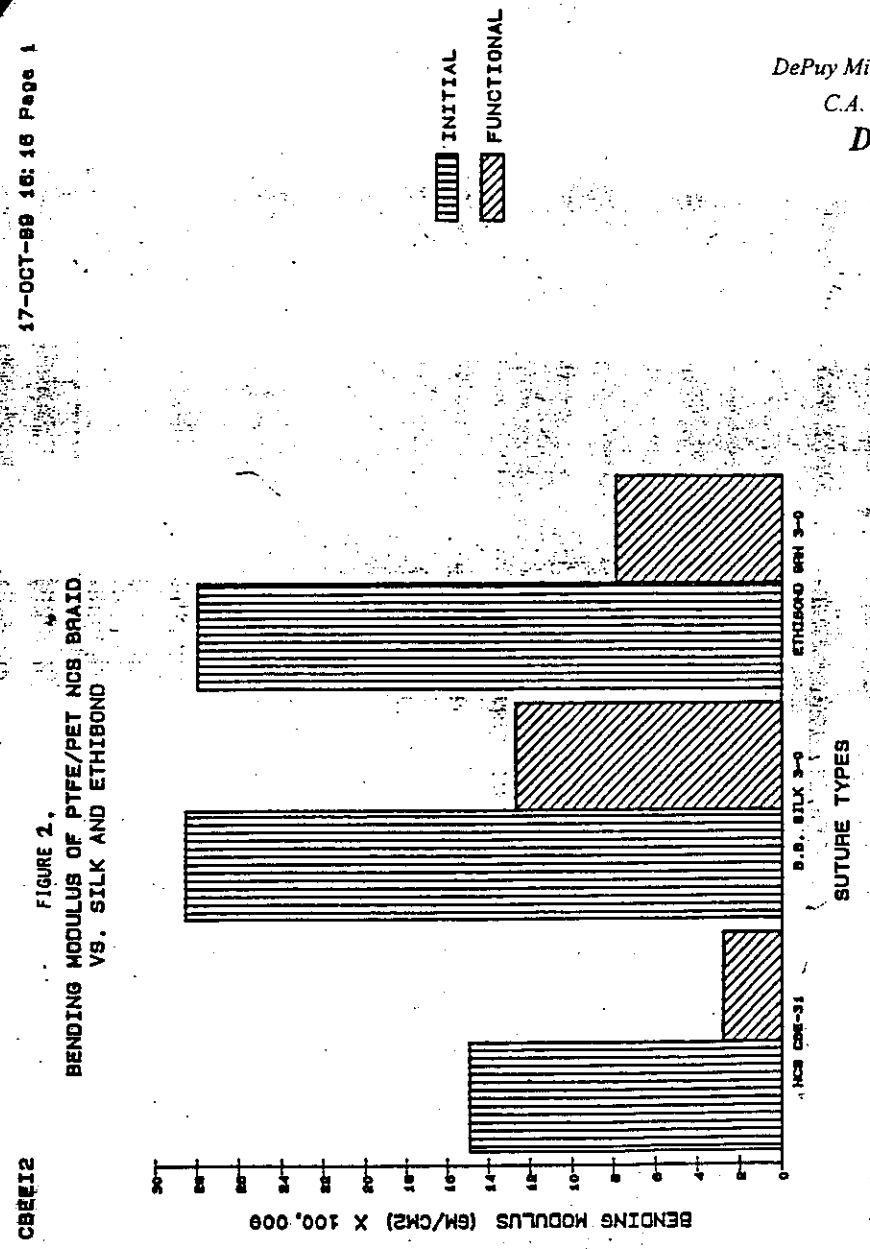

FIGURE 2.
BENDING MODULUS OF PTFE/PET NCB BRAID VS. SILK AND ETHIBOND

12/13/89

Investigator

Date 12/13/89

Witness Richard Smith

Date 2-15-90

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2175

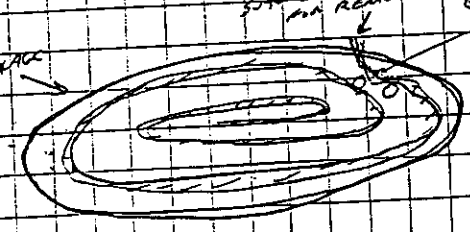
Project No. IDEA Experiment No. Date 12/19/89

Subject PLIABILIZING PINS IN SUTURE PACKAGE

Purpose TO IMPROVE PLIABILITY OF SUTURE IN USE.

IDEA: THE BENEFITS OF "MECHANICAL PLIABILIZATION" HAVE LONG BEEN RECOGNIZED TO IMPROVE THE HAND OF BRAIDED SUTURES. THE APPROACH IS TO BREAK UP THE WEAK ADHESIONS WHICH BIND TOGETHER INDIVIDUAL MULTIFILAMENTS IN THE BRAID BUNDLE. THESE ADHESIONS ACT TO REDUCE FIBER MOBILITY AND EFFECTIVELY INCREASE THE BENDING RIGIDITY OR STIFFNESS OF THE BRAID. THE ADHESIONS ARE GENERALLY DISRUPTED BY FORCING THE BRAID INTO ONE OR MORE SHARP CURVATURES WHICH HAVE THE EFFECT OF SHEARING OR SLIDING THE FIBERS RELATIVE TO EACH OTHER THROUGH THE THICKNESS OF THE BRAID. HOWEVER, THIS OPERATION IS CONVENTIONALLY PERFORMED AFTER HOT-STR., ANNEALING, OR COATING. THE BRAID EXPERIENCES ELEVATED TEMPS DURING STERIL. + PACKAGING CYCLES, WHICH CAN REFORM THE ADHESIONS. THE PROPOSED INVENTION IS TO INCLUDE PLIABILIZATION PINS OR RODS INTO THE DESIGN OF THE PACKAGE SO THAT THE MANUAL REMOVAL OF THE SUTURE IMPARTS A PLIABILIZATION EFFECT ON THE SUTURE.

IT HAS BEEN SHOWN REPEATED THAT THE PLIABILITY AS MEASURED BY THE INSTRON RING BENDING TESTER IS ALMOST ALWAYS SIGNIFICANTLY HIGHER IN THE 2ND CYCLE VS 1ST CYCLE, DUE TO THE PLIABILIZING EFFECT OF BENDING THE ONCE BACK AND FORTH. THIS EFFECT WOULD BE BENEFICIAL TO BOTH MULTIFILAMENT AND MONOFILAMENT SUTURES.



THE PACKAGE WOULD BE INJECTION MOLDED SO THAT THE PINS WOULD BE AN INTEGRAL PART.

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Investigator [signature] Date 12/19/89

Witness Crawford Britt Date 3-15-90

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C.A. No. 04-12457 PBS
DMI002668

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Book No. 2175

Project No. TEKMAT Experiment No. Date 1/8/90

Subject IN VIVO RESULTS OF SURFACE FLUORINATED VICRYL BRAID

Purpose IMPROVE THE BSR OF VICRYL w/o ANNEALING

BACKGROUND: TO IMPROVE THE HYDROLYTIC RESISTANCE OF VICRYL AND EXTEND THE BSR, VICRYL BRAID IS ANNEALED. THIS ANNEALING OPERATION IMPROVES CRYSTALLINITY, BUT ALSO CAN ADD STIFFNESS TO THE BRAID. THE APPROACH TRIED HERE WAS TO TREAT THE SURFACE TO RENDER IT HYDROPHOBIC, SO THAT WATER WOULD ADSORB AND DIFFUSE AND DEGRADE THE VICRYL AT A SLOWER RATE. TEKMAT INC OF ASHLAND MASSACHUSETTS ATTEMPTED TO SURFACE FLUORINATE VICRYL BRAID AT THREE LEVELS. NO PROCESS DETAILS ON THE LEVELS WAS MADE AVAILABLE BY TEKMAT.

RESULTS:

THE FOLLOWING TABLE SUMMARIZES THE 0, 7, 21 DAY IN VIVO RESULTS OF THE VICRYL FOR THE THREE LEVELS OF TREATMENT AND A CONTROL. THE BRAIDS WERE SCOURED BUT NOT HOT-STRETCHED OR ANNEALED. NO STATISTICAL DIFFERENCES WERE OBSERVED BETWEEN THE TREATED SAMPLES AND THE CONTROL, SUGGESTING THAT THE TREATMENT WAS NOT EFFECTIVE.

AVERAGE BREAKING STRENGTH VALUES FOR VICRYL SUTURES
AFTER SUBCUTANEOUS IMPLANTATION IN RATS.
DATA EXPRESSED IN POUNDS

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SAMPLE NUMBER	SIZE	TIME IN DAYS 0	7	21
A3801-OB-T1	2-0	12.76	6.00	0.00*
PERCENT REMAINING		100	47	0
A3801-OB-T2	2-0	13.32	5.74	0.00*
PERCENT REMAINING		100	43	0
A3801-OB-T3	2-0	14.06	6.41	0.00*
PERCENT REMAINING		100	46	0
A3801-OB-C	2-0	14.41	6.20	0.00*
PERCENT REMAINING		100	43	0

*THESE ARE AVERAGES DERIVED FROM BOTH INSTRON VALUES AND TECHNICAL JUDGEMENTS OF ZERO NECESSITATED BY UNMEASURABLE SAMPLES

MS 1/8/90

FUTURE WORK: THE TREATMENT WILL BE ATTEMPTED ON PDS MONOFILAMENTS.

Investigator [signature] Date 1/8/90

Witness Carmi Lord Britt Date 3-15-90

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Book No. 2175

Project No. BCAD Experiment No. Date 2/21/90

Subject HOT-STRETCHED MODEL BRAIDS

Purpose PROVIDE DATA FOR FORMULATION AND VALIDATION OF HOT-STRETCH MODEL

BACKGROUND: THE BRAID CAD SOFTWARE CAN CURRENTLY PREDICT KEY GEOMETRIC AND MECHANICAL PROPERTIES FOR OFF-BRAIDER SUTURE. IN ORDER TO FORMULATE THE MODULE TO PREDICT HOT-STRETCHED BRAID PROPERTIES, A MODEL BRAID WAS PROCESSED AT A VARIETY OF CONDITIONS AND CHARACTERIZED TO GIVE DIRECTION TO THE EFFECT OF HOT-STRETCH RATIO ON BRAID PROPERTIES.

EXPERIMENT:
AN 8x1, 70 den TYPE 52 DACRON POLYESTER BRAID WAS PROCESSED WITH A 34 PLIC GEAR. THE BRAID WAS HOT-STRETCHED ON THE "ETHICON" HOT-PLATE AT 400°F AT THE FOLLOWING STRETCH RATIOS: 5, 10, 15, 20, 25%.

RESULTS:
THE RESULTS ARE SUMMARIZED IN THE FOLLOWING 4 PLOTS:

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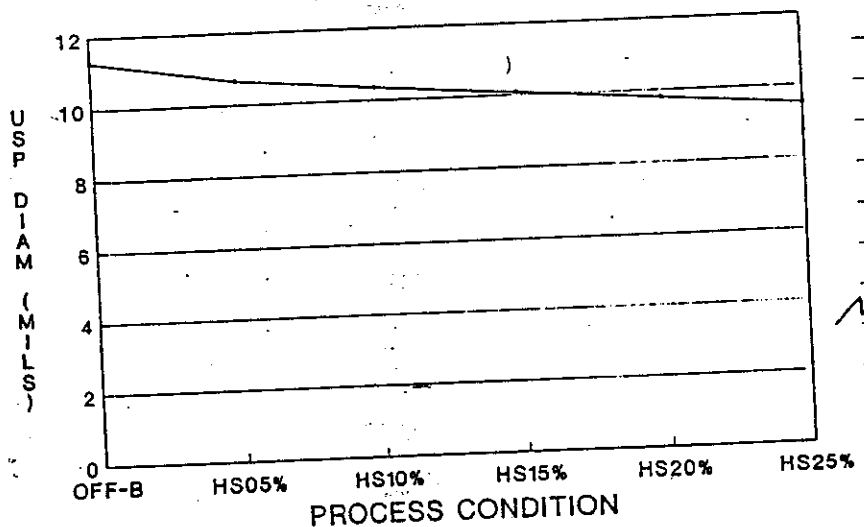
USP DIAMETER VS. HOT-STRETCH RATIO
FOR 8x1 PET MODEL BRAIDS



TYPE 52 70 DEN, 34 PG

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DMI002670

MS 2/21/90

Investigator Mark Sluter Date 2/21/90

Witness Crawford Britt Date 3-15-90

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Book No.

2175

Project No. B-CAD Experiment No. Date 2/21/90

Subject HOT-STRETCH MODELS

Purpose CONTINUED FROM P-61

PICK COUNT VERSUS HOT-STRETCH RATIO
B-CAD PET MODEL BRAID 8x1 34 PG

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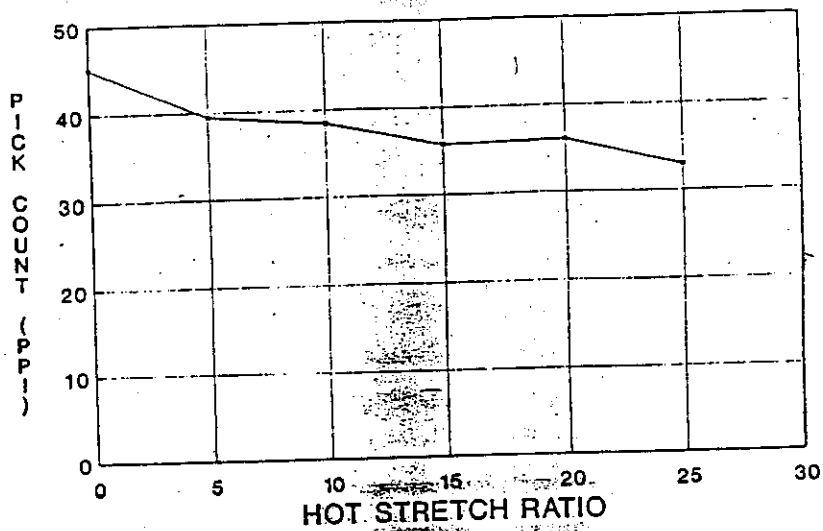
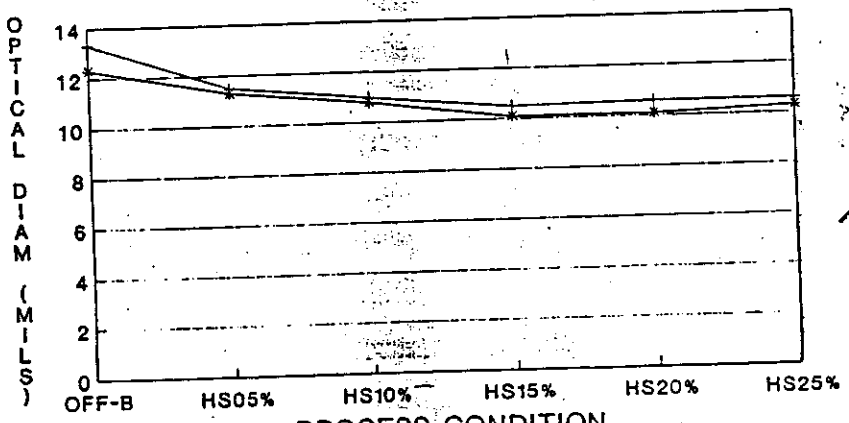


HS 0% = OFF-BRAIDER

MS 2/21/90

OPTICAL DIAMETER VS. HOT-STRETCH RATIO
FOR 8x1 PET MODEL BRAIDS



TYPE 52 70 DEN, 34 PG

MS 2/21/90

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C.A. No.04-12457 PBS
DMI002671

Investigator Date 2/21/90

Witness

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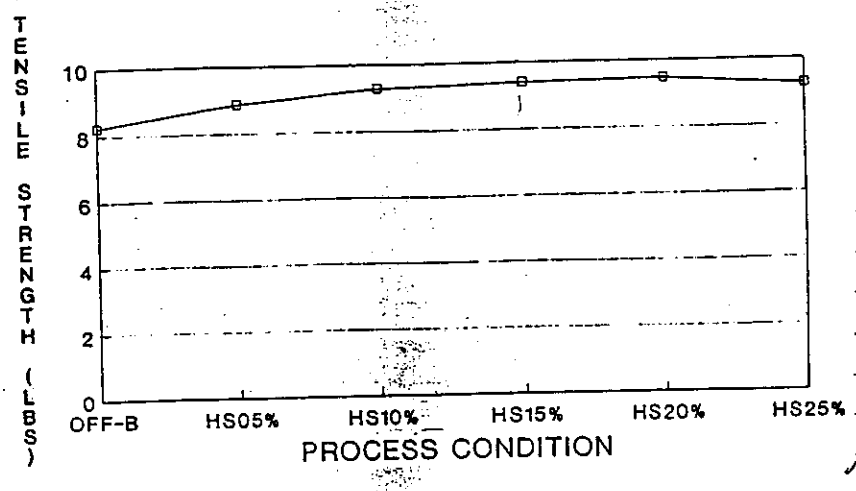
Project No. B-CAD Experiment No. Date 2/21/90

Subject HOT-STRETCH MODELS

Purpose CONTIN. FROM p-62

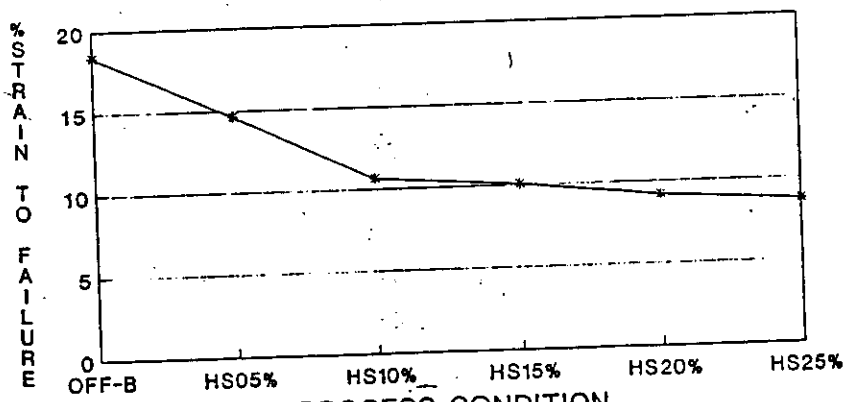
TENSILE STRENGTH VS. HOT-STRETCH RATIO FOR 8x1 PET MODEL BRAIDS



MS 2/21/90

TYPE 52 70 DEN, 34 PG
YARN THEOR. UTS (630 DEN)= 8.6 LBS

STRAIN TO FAILURE VS. HOT-STRETCH RATIO FOR 8x1 PET MODEL BRAIDS



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TYPE 52 70 DEN, 34 PG
YARN FAIL STRAIN = 13%

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DMI002672

Investigator Mark Sloan Date 2/21/90

Witness Crawford Britt Date 3-15-90

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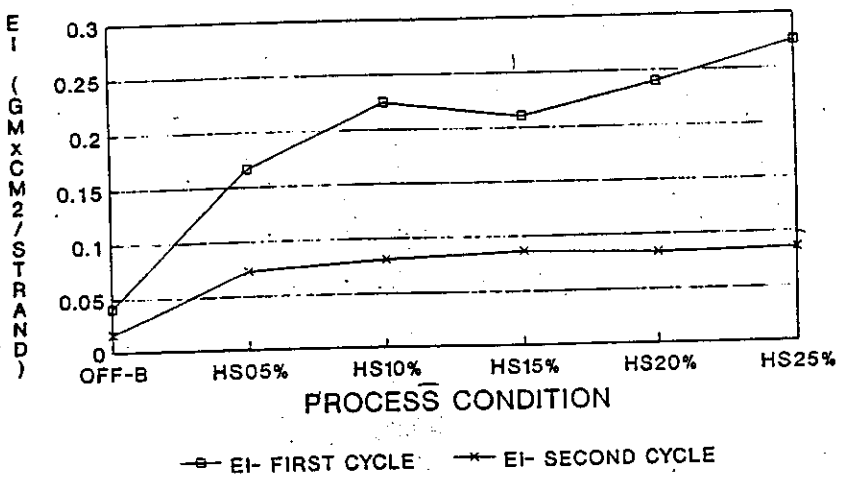
Project No. BCAD Experiment No. Date 2/21/90
Subject HOT STRETCH MODELS
Purpose CONT FROM P. 63

BENDING RIGIDITY VS. HOT-STRETCH RATIO FOR 8x1 PET MODEL BRAIDS



TYPE 52 70 DEN, 34 PG
KAWABATA PURE BENDING

MS 2/21/90

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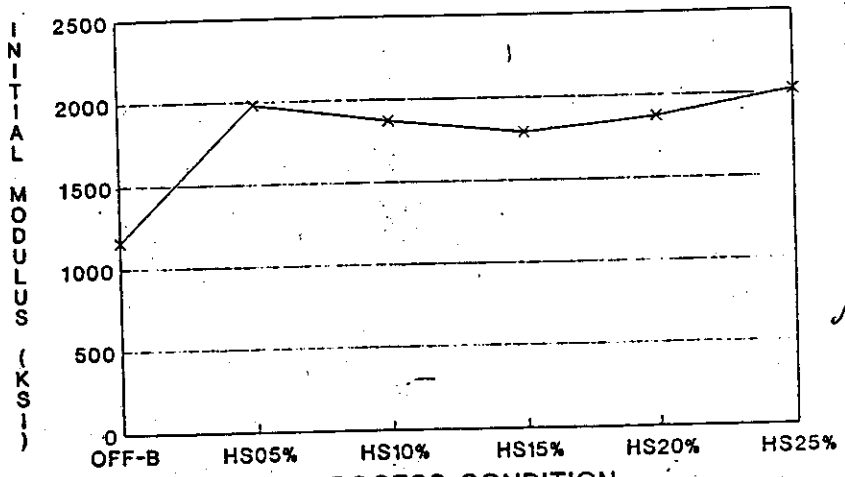
INITIAL MODULUS VS. HOT-STRETCH RATIO FOR 8x1 PET MODEL BRAIDS



TYPE 52 70 DEN, 34 PG

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C.A. No.04-12457 PBS
DMI002673

Investigator [signature] Date 2/21/90
Witness [signature] Date 3-15-90

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Book No. 2175

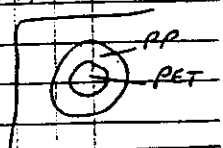
Project No. BCF - CBE Experiment No. Date 3/12/90

Subject COMPOSITE BRAID - BCF PP/PET - BICOMPONENT FIBER

Purpose PROCESSING AND PROPERTIES OF PROTOTYPE CONSTRUCTION

BACKGROUND: ONE TYPE OF COMPOSITE BRAID WHICH HAS BEEN EXPLORED INVOLVES THE BLENDING OF 2 FIBER COMPONENTS, ONE WITH HIGH LUBRICITY, AND A SECOND WITH HIGH STRENGTH. THE HIGH LUBRICITY FIBER ACTS AS A SOLID LUBRICANT WHICH ALLOWS EASIER FIBER-FIBER SLIDING WHICH HAS THE NET EFFECT OF IMPROVING PLIABILITY.

EXPERIMENT: A BRAID WAS MADE FROM A PP/PET BICOMPONENT FIBER YARN. THE FIBER WAS APPROX. 50/50 BY VOLUME PP/PET IN A SHEATH-CORE STRUCTURE WITH THE PP IN THE SHEATH. THE YARN WAS RECEIVED FROM BASF UNDRAWN, WITH A DENIER OF 104. THE YARN WAS SUBSEQUENTLY ORIENTED AT 3.0X AND 155°F TO PRODUCE A YARN WITH ≈4.5 GPD STRENGTH AND 20% STRAIN TO FAILURE. THE YARN (WAS 35 DEN AFTER DRAW) WAS BRAIDED IN A 16x4 CONSTRUCTION AT A 35 PICK ON A N.E. BUTT BRAIDER (WITH NO SPACING). THE BRAID WAS SUBSEQUENTLY HOT-STRETCHED AT 5X AND 100°F ON THE "ETHIBOND HOT-PLATE". THE BRAID WAS THEN PLIABILIZED THROUGH A SERIES OF SMALL ROLLERS AT AN INPUT TENSION OF 300 GMS.



RESULTS: THE RESULTING 2-0 BCF BRAID ~~WAS~~ HAD EXCEPTIONAL HANDLING PROPERTIES, FAIR STRENGTH AND KNOT STRENGTH VS. SILK AND ETHIBOND. THE RESULTS ARE SUMMARIZED IN THE FOLLOWING PLOTS.

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DISCUSSION:

THIS APPROACH DESERVES FURTHER CONSIDERATION, BUT WITH AN IMPROVED YARN WHICH DOES NOT STICK DURING HOT-STRETCHING. A YARN WITH A PROLENE PP POLYMER WILL BE MADE.

Investigator [signature] Date 3/12/90

Witness Crawford Britt Date 3-15-90

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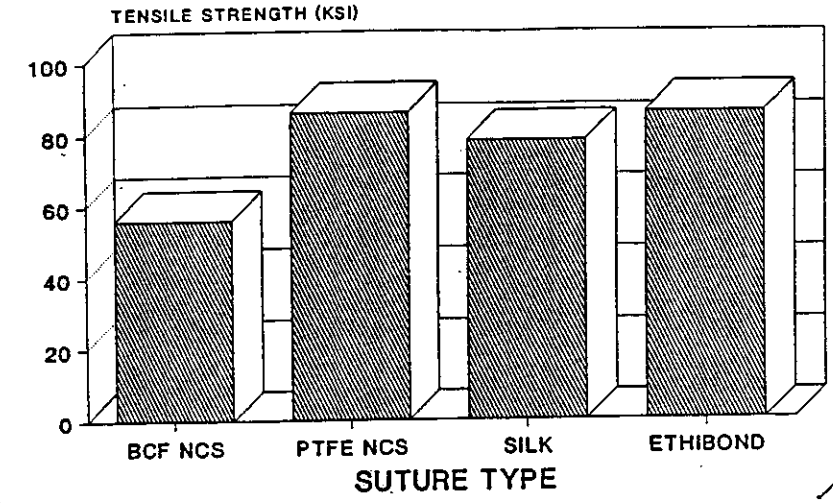
Book No. 175

Project No. BCF-CBE Experiment No. Date 3/12/90
Subject Composite Braid
Purpose Continued from p. 65

INTRINSIC STRAIGHT TENSILE STRENGTH FOR PP/PET AND PTFE/PET NCS VS. SILK AND ETHIBOND

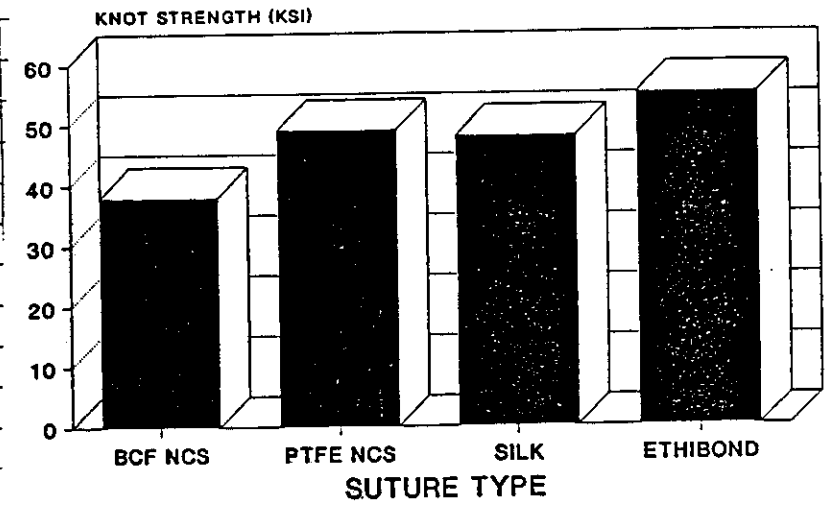


•based on USP diameter
•intrinsic tensile can be size dependent

MS 3/12/90

INTRINSIC KNOT TENSILE STRENGTH FOR PP/PET AND PTFE/PET NCS VS. SILK AND ETHIBOND

MS 3/12/90



•based on USP diameter
•intrinsic tensile can be size dependent

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DMI002675

Investigator [signature] Date 3/12/90
Witness Donald Britt Date 3-15-90

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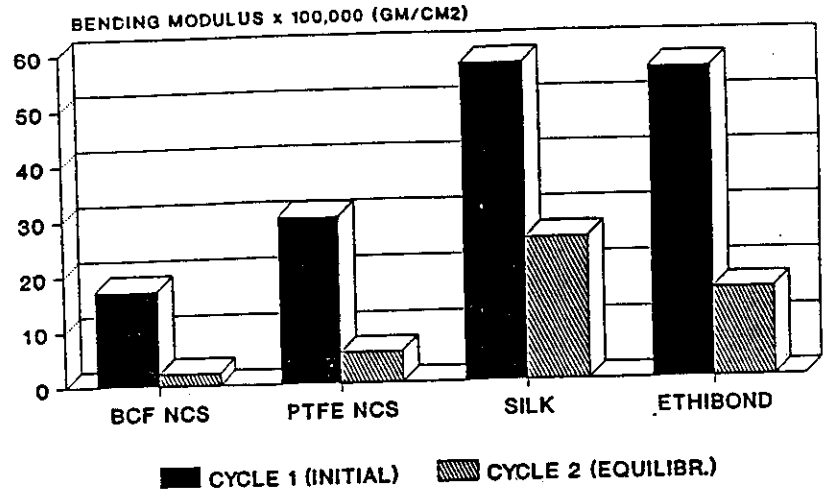
Book No. 2175

Project No. BCF-CBE Experiment No. Date 3/12/90

Subject COMPOSITE BRAID

Purpose CONTINUED FROM P. 66

PLIABILITY (KAWABATA BENDING MODULUS) FOR PP/PET AND PTFE/PET NCS VS. SILK AND ETHIBOND



3/12/90

Investigator Date 3/12/90

Witness Crawford Britt Date 3-15-90

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Book No. 2175

Project No. JJO Experiment No. Date 8/30/90
Subject ANNEALING OF AACL DEVICES
Purpose RECORD ANNEALING CONDITIONS

PURPOSE: ANNEAL THE ABSORBABLE ANTERIOR CRUCIATE LIGAMENT DEVICE FOR JJO.

MATERIALS: LOT # PLA-037-11-1
(95/5 PLA/PGA MULTIFILAMENT)

CONDITIONS: OVEN (MICROPROC CONTROLLED - 3RD FLOOR) - PER DENNIS JANIOLKOWSKI

Annealing Scheme For Continuous Loops

Side B

Seg No		Power on / N2 purge & Cooling 1	2	3	4	Set Pt	Time	Rcy	Next Seg
29	Jog	X	X	—	X	25	5S	—	30
30	Purge	X	X	X	X	25	30 m	—	31
31	Ramp	X	X	—	X	95	90 m	—	32
32	Maintain	X	X	—	X	95	15 h	—	33
33	Cool to RT_1	X	X	—	X	25	30S	—	34
34	Cool to RT_2	X	X	—	X	25	30S	239	35
35	Transfer	X	X	—	X	25	2S	—	40
40	Cool to RT_3	X	X	—	X	25	30S	—	41
41	Cool to RT4	X	X	—	X	25	30S	239	40
42	Hold	X	X	—	X	25	30S	—	42
50	Emergency	X	X	—	X	25	5S	—	50

Investigator [signature] Date 8/30/90
Witness Date

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Book No. 2175

Project No. JJO Experiment No. Date 9/7/90

Subject ANNEALING OF AACL

Purpose RECORD ANNEALING CONDITIONS

PURPOSE: SAME AS 2175-68

MATERIALS: 95/5 PLA/PGA MULTIFILAMENT FILAMENT

LOT # PLA-037-11-1 JJO: 6737-90-10

~~LOT # PLA-037-31-1~~ ~~6737-91-10~~

6737-90-10

CONDITIONS:

SAME AS 2175-68.

Investigator [signature] Date 9/7/90

Witness Date